K010083

JUN - 6 2001

Summary of Safety and Effectiveness

Submitter:

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Date Prepared:

10 January 2001

General Provisions

Trade Name: Cordis TrapEase™ Permanent Vena Cava Filter and Introduction Kit

Common Name: Permanent Vena Cava Filter and Introduction Kit

Classification Name: Cardiovascular Intravascular Filter (per 21 CFR 870.3375)

Device Classification: Class II

Name of Predicate Devices

The modified Cordis TrapEase™ Permanent Vena Cava Filter and Introduction Kit is substantially equivalent to:

- Cordis TrapEase™ Permanent Vena Cava Filter and Introduction Kit
- The LGM - Vena 30 D/U Vena Cava Filter System, B. Braun
- Simon Nitinol Filter/Straight Line™ System and Simon Nitinol Filter™ System, Nitinol Medical Technologies, Inc.
- Stainless Steel Greenfield® Vena Cava Filter, Boston Scientific Corporation

Performance Standards and Special Controls

As per 21 CFR 870.3375, the following special controls were established for cardiovascular intravascular filters: (1) "Use of International Standards Organization's ISO 10993 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing,' and (2) FDA's: (i.) "510(k) Sterility Review Guidance and Revision of 2/12/90 (K90-1)" and (ii) "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions."

Device Description

The subject device is a system that consists of a flexible, symmetrical, self-expanding vena cava filter to be deployed in the infrarenal inferior vena cava via a 6F sheathed introduction kit. The filter is designed to trap large, life-threatening emboli and therefore prevent recurrent pulmonary embolism, while maintaining caval patency. The modification to the subject device labeling, namely the removal of the contraindication which limits the implantation of theTrapEase Permanent Vena Cava Filter in those patients with an inferior vena cava smaller than 18 mm in diameter, does not affect the intended use or basic fundamental technology of the device and is substantially equivalent to predicate device labeling.

Intended Use

The intended use of the Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit is prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated,
- Failure of anticoagulant therapy in throboembolic diseases,
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced and chronic,
- and recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

This is the same intended use featured with the predicate devices.

Performance Data:

The safety and effectiveness of the modified Cordis TrapEase™ Permanent Vena Cava Filter and Introduction Kit have been demonstrated via data collected from non-clinical design verification tests and analyses. The design verification testing consisted of the following:

- Filter Migration
- Filter Fracture
- Caval Perforation
- Dimensional evaluation of the filter length – diameter relationship (One-sided filter foreshortening).

Summary of Substantial Equivalence

The design, material, components, fundamental technology and intended use featured with the subject Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit are identical and therefore substantially equivalent to the predecessor Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit (reference 510(k) #K000062). Furthermore, the Instructions for Use featured with the subject Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit is substantially equivalent to the predicate Vena Tech LGM, Simon Nitinol, and Greenfiled Vena Cava Filters with respect to an absence of a contra-indicated minimum vessel diameter.

A statement of substantial equivalence to another product is required by 21 CFR 807.87 and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the commissioner of the stated, "A determination of substantial equivalence under the Federal Food, Drug and Cosmetic Act related to the fact that the product can be lawfully marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Federal Register 42, 50 et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2001

Cordis, Corp.
c/o Ms. Karen Wilk
Senior Regulatory Affairs Associate
P.O. Box 4917
Warren, NJ 07059

Re: K010083/S1
Trade Name: Cordis TrapEase™ Permanent Vena Cava Filter and Introduction Kit
Regulation Number: 870.3375
Regulatory Class: II (two)
Product Code: DTK
Dated: April 5, 2001
Received: April 6, 2001

Dear Ms. Wilk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K010083

Device Name: Cordis TrapEase™ Permanent Vena Cava Filter and Introducer

Indications For Use: TrapEase™ is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced;
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010083

(Optional Format 3-10-98)